

CLAIMS

1. A method for treating a subject having non-fungal induced mucositis of the distal intestinal tract, comprising administering locally to the distal intestinal tract of the subject an anti-fungal azole compound in an amount effective to reduce or eliminate the non-fungal induced mucositis of the distal intestinal tract.
2. The method of claim 1, wherein the effective amount comprises in a single dosage about 2,000 mg to about 10,000 mg of the anti-fungal azole compound, at a frequency of administration from four times a day to once a month.
3. The method of claim 1, wherein the non-fungal induced mucositis of the distal intestinal tract is selected from the group consisting of: pouchitis, ulcerative colitis, Crohn's disease, allergic colitis, autoimmune colitis, autoimmune enteropathy, bacterial colitis, diversion colitis and lymphocytic colitis.
4. The method of claim 1, wherein the non-fungal induced mucositis of the distal intestinal tract is pouchitis.
5. The method of claim 1, wherein the mucositis of the distal intestinal tract is non-microbial induced.
6. The method of claims 1, wherein the dose is from 2,500 mg to 10,000 mg at a frequency of from twice a day to once every two weeks.
7. The method of claims 1-6, wherein the subject is a human.
8. The method of claim 7, wherein the anti-fungal azole compound is selected from the group consisting of: anti-fungal imidazole compounds, anti-fungal triazole compounds and anti-fungal nitroimidazole compounds.

9. The method of claim 8, wherein the anti-fungal azole compound is an anti-fungal imidazole compound.
10. The method of claim 9, wherein the anti-fungal imidazole compound is clotrimazole.
11. The method of claim 1, further comprising administering to the subject an amount of one or more non-azole compounds effective to treat the non-fungal induced mucositis of the distal intestinal tract.
12. The method of claim 11, wherein the non-azole compounds are selected from a list consisting of anti-inflammatory or anti-bacterial compounds.
13. An article of manufacture, comprising packaging material and an anti-fungal azole compound, wherein the article of manufacture further comprises a label or package insert indicating that the anti-fungal azole compound can be administered to a subject for treating a non-fungal induced mucositis of the distal intestinal tract.
14. The article of manufacture of claim 13, wherein the anti-fungal azole compound is present in a unit dosage of between about 2,000 mg and about 10,000 mg.
15. The article of manufacture of claim 13, wherein the label or package insert indicates that the anti-fungal compound can be administered to a human subject.
16. The article of manufacture of claim 15, wherein the label or package insert indicates that the anti-fungal compound can be administered for treating a non-microbial induced mucositis.

- 40 -

17. The article of manufacture of claim 15, wherein the anti-fungal azole compound is present in a unit dosage of about 2,500 mg to about 10,000 mg.
18. The article of manufacture of claim 15, wherein the anti-fungal azole compound is an anti-fungal imidazole compound.
19. The article of manufacture of claim 18, wherein the anti-fungal imidazole compound is clotrimazole.
20. The article of manufacture of claims 13-19, wherein the article of manufacture further comprises an enema component.
21. The article of manufacture of claim 20, wherein the enema component is either or both of an insertable enema tip or a container adapted for fluid connection with an insertable enema tip.
22. The article of manufacture of claim 21, wherein the container is a soft squeeze bottle.
23. The article of manufacture of either claim 21 or 20, further comprising of one or more of: a flow-control valve, a reflux-prevention valve, and a replaceable protective shield.
24. The article of manufacture of either claim 21 or 23, wherein the anti-fungal azole compound is in a liquid formulation contained in the container.
25. The article of manufacture of claim 24, wherein the anti-fungal azole compound is an anti-fungal imidazole compound.
26. The article of manufacture of claim 25, wherein the anti-fungal imidazole compound is clotrimazole.

- 41 -

27. The article of manufacture of claim 26, wherein the anti-fungal compound is in a formulation that is ready to use.
28. The article of manufacture of claim 26, wherein the article of manufacture is disposable.
29. The article of manufacture of claim 26, wherein the enema component is latex free.
30. The article of manufacture of claim 27, wherein the formulation is for rectal administration.
31. The article of manufacture of claim 20, further comprising one or more non-azole compounds that can be administered to a subject for treating a non-fungal induced mucositis of the distal intestinal tract.
32. The article of manufacture of claim 31, wherein the non-azole compounds are selected from a list consisting of anti-inflammatory or anti-bacterial compounds.
33. A pharmaceutical composition comprising an enteric coating containing an anti-fungal azole compound.
34. The pharmaceutical composition of claim 33, wherein the enteric coating releases the anti-fungal azole compound in the distal intestinal tract.
35. The pharmaceutical composition of claim 33, wherein the enteric coating releases the anti-fungal azole compound in a pH greater than 5.5.
36. The pharmaceutical composition of claim 33, wherein the enteric coating releases the anti-fungal azole compound in a pH greater than 7.

37. The pharmaceutical composition of claim 33, wherein the pharmaceutical composition is administered to a human for treating non-fungal induced mucositis.
38. The pharmaceutical composition of claim 33, wherein the pharmaceutical composition is administered to a human for treating non-microbial induced mucositis.
39. The pharmaceutical composition of claim 33, wherein the anti-fungal azole compound is present in an amount of about 2,000 mg to about 10,000 mg.
40. The pharmaceutical composition of claim 33, wherein the anti-fungal azole compound is present in an amount of about 2,500 mg to about 10,000 mg.
41. The pharmaceutical composition of claim 33, wherein the anti-fungal azole compound is an anti-fungal imidazole compound.
42. The pharmaceutical composition of claim 41, wherein the anti-fungal imidazole compound is clotrimazole.
43. The pharmaceutical composition of claim 33, further comprising one or more non-azole compounds for treating a non-fungal induced mucositis of the distal intestinal tract.
44. The pharmaceutical composition of claim 43, wherein the non-azole compounds are anti-inflammatory or anti-bacterial compounds.